**In the Matter Of:**

NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY

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# DEPOSITION OF

# DAVID CHASON

*December 21, 2016*

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UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF MASSACHUSETTS

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| IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION | MDL NO. 2419 |
| This Documents Relates to: All Cases against the Box Hill Defendants | Master Docket 1:13-MD-02419-RWZ |

# DEPOSITION OF DAVID CHASON

WEDNESDAY, DECEMBER 21, 2016
10:00 a.m.

Law Office of Peter G. Angelos
One Charles Center
100 North Charles Street
Suite 2200
Baltimore, MD 21201

Before: Linda Bahur, RPR

But you'd agree that thousands of other customers of NECC were ordering drugs in the same way as Dr. Bhambhani without using patient-specific prescriptions?

MR. COREN: Objection to form.

Q That's what was happening in actuality, right?

A What's happening in actuality --

MR. COREN: Objection to form.

Q Okay.

MS. STEINER: All three of you were talking at the same time. I know I didn't hear the respective answer, so I'm sure the court reporter is having trouble as well.

THE REPORTER: What was your answer?

MR. KIRBY: He said yes.

THE WITNESS: Yes. Sorry.

BY MR. KIRBY:

Q Is it your opinion that all of those healthcare providers who didn't order drugs from NECC using this patient-specific prescription breached the standard of care?

MR. COREN: Objection to form. You can respond.

A Yes. And they put their patients at risk.

A No.

Q Okay. Let's look at Section B on page 4, "Compliance with regulations." You talk about -- well, you tell me what the deviations are here.

A When she began to use a compounding pharmacy, it wouldn't have been appropriate for her to determine whether she was in compliance with Maryland regulations, which it does not appear from any documentation that she did.

Q Okay. Now, are you aware that she had been ordering from NECC, a compounder, for I don't know, several years, a number of years, prior to this in the same way that she's ordering -- that she was ordering from NECC when she got the contaminated drugs?

A She should have done the due diligence when she started to order from NECC, not when the contamination occurred.

Q Okay. And I think you had said earlier that you did some Internet research, right, on prescription writing or something? Remember that? And you said you didn't -- I think you said, and correct me if I'm wrong, that you didn't find anything -- eventually I think you got a document from Plaintiffs' counsel that was a World Health

Organization document from Europe or something that talked about it, right?

A Correct.

Q So what is it exactly that Dr. Bhambhani should have done? Start with that.

A In relation to compliance with regulations?

Q Correct.

A That aspect of it?

Q Correct.

A If she had done any research on her own part or had received training as we offered to our residents in the hospital, she probably would have known that the relationship that she was to establish with a compounding pharmacy was not meeting legal requirements.

Q And so let's -- what do you think she would have -- so that's what she would have found if she did the research?

A Uh-huh.

Q You didn't find that, though, did you, when you did your research?

A I didn't find it until the WHO. But I also knew my history from having taught residents told me that that's a critical aspect. And it was

validated by, you know, the chiefs of the various departments of the hospital. The chief of medicine, chief of surgery, all wanted us to focus on good prescription writing practices.

Q And I guess where I'm losing you is that you said you did research and didn't find anything, right? So wouldn't it be reasonable to think that if Dr. Bhambhani did the same research that you did, she wouldn't have found anything?

And by the way, the World Health Organization article that you found you said you got after you drafted your report, so it wasn't even the basis for your report. So isn't it more reasonable to suggest that Dr. Bhambhani would have had the same outcome as you did --

MR. COREN: Objection as to form.

Q -- if she had done that research?

A I can't know that.

Q You can't know that one way or the other, right?

A Correct.

Q Okay. And so let's then take another scenario. Let's say that she did research and found out that she needed to use patient-specific prescriptions when ordering from NECC, and she did

administer drugs.

Q But the nomenclature itself, what she used -- I know you have an issue with the nomenclature she used. But that didn't change the drug given and make it contaminated, did it?

A No, of course not. But it didn't -- didn't lead me to believe that she practiced -- practiced in the most appropriate way.

Q Understood that that's your position. But that doesn't mean that the way in which she used -- the way in which she identified the drug, that that caused her patients to get sick?

MR. MINTZER: Objection to form.

A I wasn't inferring anything of that nature.

Q I understand. I just need to know one way or the other. So if you're not inferring that, that's fine. So you're not inferring that, correct?

A Correct.

Q Okay. Unless you have anything else on that topic, let's go to the fourth issue that you had, "Research on compounded products."

A Uh-huh.

Q Can you explain what your issue is on that topic?

A From the documentation it indicated to me that Dr. Bhambhani didn't conduct any research to confirm that this company was capable of compounding the product. And it didn't appear from her responses that she understood the difference between compounding and manufacturing.

Q Okay. So what exactly was she supposed to have done, specifically?

A My point here was that she was responsible for confirming that the product that she was using was safe and appropriate for her patients, and it didn't appear to me from her documents that she had done this.

Q It was, we can agree, eight years or so, right? Her use of NECC's MPA for eight years was safe, correct?

MR. COREN: Objection to form.

A She was lucky enough that for an earlier period that she didn't receive contaminated product. But that doesn't remove the idea that she could have done research to determine whether they were appropriate vendors.

Q But you also have to have some luck to not, you know, have an adverse event from a drug that you get from an FDA supplier, too, right? It's not

that just because you're getting it from a compounder means that you can't trust them, right?

MR. COREN: Objection to form. You can respond.

A When you're bypassing the controls that the FDA places on the production of a product, the physician assumes a higher set of responsibility and there's more risk. So they need to do more due diligence.

Q But there were entities that did do -- that did inspect NECC, right?

MR. COREN: Objection to form.

A I don't know that.

Q So you weren't provided any information about inspections done by Brigham and Women's Hospital?

A That was outside the scope of what I was focused on. I was focused on her behavior and her actions.

Q Well, you just said, I think, and I could be wrong, correct me if I'm wrong, that if she had done research she would have found out that NECC couldn't provide safe drugs or would provide risky drugs. Didn't you just say that?

A The opportunity was there for her to do

that.

Q Right. Right. But if Brigham and Women's did the inspection and came away finding that there was no issue with NECC, and they were permitted to continue to order drugs, then wouldn't that be contrary to what you just said?

MR. MINTZER: Objection.

MR. COREN: Objection to form. Misstates the record. Also an incomplete statement of the record.

A I'm sorry I'm laughing, but I'm lost.

MS. STEINER: It's all designed to make you lost.

Q So then I have to ask the question again.

A I know, but this is going on long enough that the answer that I can give you is that she had an obligation. I don't know what occurred in Brigham and Women's, and I can't speak to that.

Q So if she had done the proper research, what would she have found about NECC?

A I don't know. But she could have -- the possibility exists she could have found out that they were a subpar producer of product or that she was breaking the standard of care with patient, physician and pharmacist relationships. And that would have

led her to make some other decisions.
Q So I understand, theoretically, if she had done that, she may theoretically have found out that NECC wasn't a safe supplier of drugs, right? It's possible that she could have done that. But sitting here today you can't tell us one way or the other that she would have found that out?
MR. COREN: Objection as to form.
A Theoretically, I could be sitting on that side of the table, too, and ask your question. But the question doesn't make sense to me.
Q I'm just trying to find out what your opinion is.
A It's circular.
Q And I think that you said it's possible she may have found out --
A And we can't know what would have occurred.
Q Okay. That's all I need to me. We just can't say one way or the other.
A Okay.
Q Okay. We're getting good at this.
A We're getting good at this. That's what worries me the most.
Q If other entities had inspected or done

MR. COREN: Objection to form.
MR. MINTZER: Objection.
A I am not saying that.
Q Let's move onto the Box Hill Surgery Center. You listed in here, "Development of surgery center policies and procedures."
Can you explain what you think the issues are in this topic?
A The policies and procedures are, in any healthcare setting, a critical component of making sure that the organization meets the standards that it has set. And the policies and procedures were provided by a vendor in a template form. And based on the responses and my review of them, they were not tailored to the Box Hill Surgery Center in such a way as to be as functional as they should be.
Q Okay. Bear with me for a second.
A After this question I'd like to stop for a minute.
Q Sure. Sure.
MR. KIRBY: Why don't we take a break now?
THE WITNESS: Okay.
(Break taken from 3:42 to 3:47 p.m.)
BY MR. KIRBY:
Q So Mr. Chason, I think before we left, you

were giving me your criticisms with regards to this topic A, and you suggested something about it was inappropriate for getting a template, I think, provided by a business management vendor and that Dr. Bhambhani, while it was a good starting point, she should have refined and customized that template to meet the needs of the particular organization. Remember saying that?

A Correct.

Q And my confusion is, because I thought I read in her deposition, and you may have seen it also, but I thought that she had testified in her deposition that although she got a template, that she actually went back and changed it. And as a matter of fact, she reviewed it and made changes every year.

Do you recall seeing that in her deposition?

A Yes, I saw that. And yet she didn't make changes in it and she didn't follow it in regards to some of the standardized information provided in it. So I believe she made that statement that she did review it, but she didn't make substantiative changes that would have improved it.

Q And I think, in fact, in her deposition she testified right there after that she had modified

policies and procedures for her Medicare and State survey.

Do you remember seeing that?

A I don't remember seeing that specifically.

Q Assuming that's in there, are you familiar with the Medicare and/or State survey?

A No.

Q So you wouldn't know one way or the other what they do to audit an ambulatory surgery center, correct?

A Correct.

Q And actually, in your opinion near the bottom of that section A, I think you say, "The services provided in a surgery center do not come under the purview of the Maryland Board of Pharmacy."

Do you see that?

A Correct.

Q And so are you saying that even though you're offering these opinions, you know, this is an ambulatory surgery, it's not a pharmacy?

MR. COREN: Objection.

A No, that's another reference. In that issue she was calling herself the -- by one of the titles she assumed was, like, pharmaceutical care manager or something of that nature. And my

reference was that that's an incorrect title to provide herself, and there wasn't anything in Maryland law that permitted that or that sanctioned it.

Q Okay. And were you aware that Box Hill Surgery Center was accredited with the AAAHC?

A I believe I saw that in the documentation, yes.

Q Okay. Do you know what AAAHC is?

A No.

Q So you wouldn't know the process by which --

A Correct.

Q And let me just finish my question for the record.

But you wouldn't know --

A Let's see, 10 of 4:00. I'm starting to give your answers before you ask them. I apologize.

Q You wouldn't know the process that the AAAHC -- and by the way, it's the Accreditation Agency for Ambulatory Health Centers. That doesn't refresh your memory about AAAHC?

A No.

Q So you wouldn't know what AAAHC does when

they come in to audit an Ambulatory Surgery Center, would you?

A Correct.

Q And so you wouldn't know whether they evaluate an ambulatory surgery center's policies and procedures, correct?

A I do not know what they do.

Q Okay. And to the extent -- did you also see that Dr. Bhambhani was AAAHC-certified not only before the meningitis outbreak, but then she got reaccredited by them, it was a certain number of year process. It was routine, but that she got reaccredited immediately after the meningitis outbreak?

MR. MINTZER: Objection to form.

MR. COREN: Objection to form.

A I am not aware of that.

Q So as far as you know, then, AAAHC could have audited Dr. Bhambhani, evaluated her policies and procedures and said that they were fine?

MR. COREN: Objection to form.

Q Correct?

A I have no knowledge of what they evaluated.

Q So if the testimony in Dr. Bhambhani's

deposition was that AAAHC -- I'm paraphrasing -- leaves no stone unturned, they come in, they check the policies and procedures, they open up the medicine cabinets, look at the medicine, they evaluate everything about the ambulatory surgery center before certifying them, you wouldn't have any reason to dispute that, would you?

MR. MINTZER: Objection.

MR. COREN: Objection to form.

Q You wouldn't have any reason to dispute that, would you?

MR. MINTZER: Same objection.

MR. COREN: Same objection.

A I can't comment on something that I haven't evaluated their standards. So it's not something that I would be able to venture a guess about, make a statement about.

Q Pardon me. So I understand that you say you can't venture a guess, but that you also don't have any reason to dispute that?

MR. COREN: Objection to the form.

MR. MINTZER: Objection to the form.

Q The testimony that was in her deposition.

MR. MINTZER: Same objection.

Q Correct?

MR. MINTZER: Same objection.
MR. COREN: Same objection.
A I don't think I can answer that question because I don't know what their standards are and I don't know how strictly they adhere to the kind of practices that would have provided some patient safety.
Q Being provided -- you were provided with her deposition by Plaintiffs' counsel, correct? You reviewed Dr. Bhambhani's deposition, correct?
A Yes.
Q You would have seen in her deposition that she was certified by AAAHC, correct?
MR. COREN: Objection to form.
MS. STEINER: That's a yes?
A That's a yes.
MS. STEINER: You're nodding, he's coughing. I heard no answer, so that's my job.
A Being the police officer is tough, I see.
MS. STEINER: That's why I'm wearing the black and white.
Q But yet if you're saying you're not familiar with AAAHC, you didn't ask the Plaintiffs' attorneys for any information to support your opinions with regards to the policies and procedures

and that kind of stuff, right?

MR. MINTZER: Objection to form.

A I conducted my review of the policies and procedures in the light of the way a pharmacist would develop the policies and procedures in the hospital setting that would be compliant with joint commission accreditation rules. And to me they didn't meet that standard.

Q Understood. But what a pharmacy would do or a hospital pharmacy would do under the joint commission standards, not standards of an ambulatory surgery center?

A Everyone has their own standards, but there are things that are similar in them, like the use of multidose vials. And relative to that, I didn't think this was a well-done -- well-maintained policy.

Q Is there anything else about section A that you've talked about that we haven't discussed? Any opinion that you have that we haven't discussed?

A Other than the one reference that their infection control procedures contain references to entities that did not exist in a single practice center. So that is one indication to me that they

were still using a packaged product that they hadn't tailored to their needs.

Q Okay. And all of the basis for your opinions in this section are included here in your report or we've discussed them, correct?

A Correct.

Q Let's look at the vendor review process in section B, bottom of page 5. What are your opinions in regards to this topic?

A It's a very pointed, succinct statement I tried to make here regarding whether there was actually any process that the surgery center used to evaluate all vendors, not just pharmaceutical vendors. And I didn't see what I thought was an ongoing and thorough monitoring process for all products, all -- not just products, but personnel, et cetera.

Q Okay.

A That's why that's there. It's referred to in her deposition. It refers to her deposition.

Q Let me make sure I understand. So you're criticizing Dr. Bhambhani because she didn't have a review process in place for other supplies or employees or things like that?

A In this case, vendors.

Q Okay. Are you referring to vendors for drugs, suppliers of drugs?

A Med-surg supplies. Anything that she used in her practice that was a -- well, let's call it a reuse -- not a reusable product, but all of the supplies that she used. I didn't see any controls that I thought were appropriate.

Q Okay. Could Dr. Bhambhani rely on a wholesaler to vet suppliers -- or to vet vendors for supplies?

A If she had a vendor -- my take on it was she was using multiple vendors and, therefore, the responsibility fell on her.

Q For example, McKesson --

A That's one.

Q -- would that be appropriate?

A Right.

Q And I think you said, correct me if I'm wrong, a while back, that Good Samaritan Hospital relied on wholesaler distributors to vet suppliers -- to vet vendors for supplies?

MR. COREN: Objection to form.

Q Okay.

A But there's also, you know, manufacturers that the wholesaler distributes that she should make

A That's not a conclusion I can reach.
Q You just can't say one way or the other?
A That's not a conclusion I can reach.
Q Okay. Is there anything else about this topic that we haven't discussed?
A No.
Q Okay. I think we're on to storage and refrigeration practices.
Can you tell any what your criticisms are here?
A There are a couple of components there. One was that products that are stored should be away from patient care areas during storage because the potential for contamination is greater when they're not separated. You don't necessarily store your drugs -- it's like storing your food and other things in the same room. It's a good practice not to do that.
In addition, there were compounded products that I'm believe should have been refrigerated and weren't. There were vials that had been opened to be used a second time, and they should have been refrigerated.
So it was my conclusion that storing product under refrigeration would have reduced the

potential for those contamination to be as significant. The best thing to grow bacteria and fungi is to leave them unrefrigerated.

Now, their statement, I believe -- in here, I think is contradicted. I don't believe that to be the case. But she also used vials more than once and didn't store them in refrigeration. That is really a failure.

Q We'll talk about that in one second. You referred just a second ago to 1619-6, this marketing material that you reviewed with regards to NECC's representation about their products, correct?

A Uh-huh.

Q And what does it say in the middle of the page under storage? It says "room temperature," doesn't it?

A Uh-huh.

MS. STEINER: That a "yes"?

A That's correct, it says that. I don't believe that to be a correct statement.

Q Okay. Well, NECC is representing to their customers that proper storage for the MPA is room temperature, aren't they?

A In this document, yes.

Q So you as a pharmacist don't believe that

have determined whether accepting that statement is valid. That would have been something I would have thought she might look into.

Q And Dr. Bhambhani testified on this issue. I think she was questioned extensively by Plaintiffs' counsel, and she testified in detail in her deposition as to the actual practice that she used, didn't she? Did you see that in there?

A I reviewed her testimony, yes.

Q And we can look at it if you want, but I believe that she testified that she may have used it on a limited number of patients if they were coming in in a short time after. If she had took long breaks or there weren't patients coming in for a while or it was the end of the day, that she got rid of it, correct? Can we agree that she didn't use it over multiple days?

A But that's still a breach of protocol.

Q Okay.

A She should not have drawn fluid out of it twice.

Q Okay. And I think she also testified as to her aseptic technique, that she always used a new needle; that if she had to go back to the vial, she would get a new needle. If she dropped that needle

that she'd already drawn up solution in on the floor, she threw the vial away and got a new vial. And that in between sticks with the syringe, that it was swabbed with alcohol.

Do you remember seeing that?

A Yes.

Q Okay. But it's your opinion that Dr. Bhambhani shouldn't have been using it this way, that that was breach of the standard of care?

A Yes.

Q Okay. I want to refer you to an article that was, I think, provided by Plaintiffs' counsel to me yesterday.

(Exhibit No. 1619-10 was marked for identification.)

MR. KIRBY: And we will mark it as 1619-10?

MS. STEINER: Yes.

THE WITNESS: Also a gate-keeper.

MS. STEINER: I serve many roles.

BY MR. KIRBY:

Q And for the record, can you identify what this is?

A It's an editorial addressing the issue of the price of cost savings, written in June 2008.

A Correct.

Q And it's not your opinion -- just so I'm clear. I understand you're saying there's an increased growth of organisms. You're not suggesting that if Dr. Bhambhani had followed this procedure that you say is the standard, that that would have negated any contamination that was in the vials, are you?

A No.

Q Let's look at section D, "Errors and documentation of product use." Describe for me your opinions and the basis for your opinions in this section.

A One of the preprinted forms that were used that Dr. Bhambhani would then complete sections of in her handwriting had errors in the -- first of all, they said they were Depo-Medrol 80mg, which they weren't. And then in that blank space she would insert the volume of product. And sometimes she would insert incorrect information that in one example she put in 40, which I'm sure she meant was 40mg. But she was not using her own terminology correctly that her document called for.

So there was several cases where I saw that she had written -- handwritten in preprinted

form information that was incorrect.

Q Can we at least agree up front that the documentation in Dr. Bhambhani's medical records didn't cause the MPA to become contaminated at NECC and didn't cause her patients to get meningitis or some other infliction?

A Yes.

Q Okay. Does that provide the basis for all your opinions for that section?

A Yes.

Q Let's look at section E, "Tracking of patient-specific drug lot numbers and expiration dates."

What's the basis for your opinions there? What's your criticisms first?

A Well, because there was no direct triad of patient/physician/pharmacy linkage, she could not tell the actual identity of the vial used on any individual patient, and as a result, she didn't have good documentation of who had received which contaminated vials.

Now, it became obvious when the disease state hit and they reacted. But she would have been able to more quickly respond with knowledge of what vials had been used for which patients.

This practice is a common practice to identify the lot number and expiration date on patient records, when appropriate, or have a way of tracking it if you can.

Q And you're saying the standard requires putting down the lot number and --

A I'll use the example if one of your children received a vaccine tomorrow, and this practice was before this, if you looked at the physician's records it would have either a preprinted label or a handwritten lot and expiration date on the child's medical record indicating that that lot number and expiration date were administered to that child.

Q And you'd agree with me, wouldn't you, that there has been an extreme level of increased scrutiny over compounding practices and ordering practices since the NECC meningitis outbreak, right?

MR. COREN: Objection to form. Go ahead.

A That practice was one that was in effect before this occurred, and has become, as you said correctly, has become much bigger of an issue in recent years. But it still existed before that.

Q And do you recall in your review of Dr. Bhambhani's deposition that Dr. Bhambhani

Q And is it your opinion -- or you'd agree that that didn't cause harm? Her documenting in the medical records didn't cause the MPA to become contaminated at NECC, and it didn't cause her patients to develop meningitis or die, did it?

MR. COREN: Objection to form.

A I'd like to say how many times can you ask that same question and still expect me to give you a different answer? I think we've done that like -- I'm up to like 40 times that you've asked that question that way. And I would just like to protest that I think that that's badgering me.

Q In fairness -- and I'm not intending to badger you, Mr. Chason, trust me. In fairness, it's a different question with regards to each of the criticisms you have. I keep asking you about that aspect, too. And I say specific to this.

And so if your answer is the same as the others, then that's fine. You know, you can just say no, it didn't cause harm and I'm perfectly fine with that.

A Okay.

MR. MINTZER: Objection to form.

Q So just so the record is clear, was that a "no," this specific issue with documenting in the

medical records didn't itself cause the contamination or cause meningitis?

MR. COREN: Objection to form.

A Every one of her processes that I delineated in this document I believe contributed to her not providing an adequate level of care. No one was a causative factor. And if NECC hadn't been in the mix, maybe none of this would have occurred.

Q So she documents in her medical records after she performs the care, right?

A That's the typical process, yes.

Q Right. So her documenting the procedures that she did in her medical records didn't in and of itself affect the patient that she gave the injection, did it?

A It's depending on the time lapse between doing things, because physicians can forget what they did or -- you know, and there were a number in the medical records, there are a number of steps that were shown that she went through in documentation after the fact. So those were ticklers and reminders to help her do that. So I guess the answer to your question is "yes."

MR. KIRBY: Off the record.

(Record read by the reporter.)

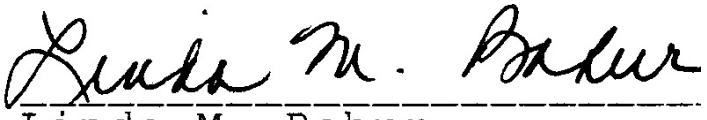
STATE OF MARYLAND )

COUNTY OF HARFORD )

I, Linda Bahur, a Notary Public of the State of Maryland, do hereby certify that the deposition of DAVID CHASON took place before me at the time and place herein set out.

I further certify that the proceeding was recorded stenographically by me and this transcript is a true record of the proceedings.

I further certify that I am not of counsel to any of the parties, nor an employee of counsel, nor related to any of the parties, nor in any way interested in the outcome of this action.



Linda M. Bahur

Linda M. Bahur

My commission expires 8/27/2019

Dated: January 5, 2017